UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A.,	:	
Plaintiff,	:	Civil Action No. 14-4274 (SRC)
v.	:	(Consolidated)
TEVA PHARMACEUTICALS USA, INC. et al.,	:	**OPINION & ORDER**
Defendants.	:	

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiff Helsinn Healthcare S.A. ("Helsinn") and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva"). In this consolidated patent infringement action, the parties seek construction of claim terms in U.S. Patent No. 8,729,094 ("the '094 patent"). For the reasons that follow, this Court adopts Teva's proposed construction.

BACKGROUND

This case arises from a patent infringement dispute involving a pharmaceutical treatment method patent. Helsinn owns U.S. Patent No. 8,729,094 (the "'094 patent") directed to, among other things, a method for reducing chemotherapy-induced nausea and vomiting using palonosetron, a compound which Helsinn markets under the brand name Aloxi®. Teva has submitted ANDA No. 090713, which seeks FDA approval to engage in the commercial manufacture and sale of generic palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent.

The present dispute over the '094 patent is one piece of a larger group of cases involving

various palonosetron patents and various pharmaceutical companies. In brief, Judge Cooper of this Court, after conducting a trial in a subset of related cases, had issued a judgment that found a number of other palonosetron patents (but not the '094 patent) valid and infringed. Teva appealed this judgment and, on May 1, 2017, the Court of Appeals for the Federal Circuit reversed the judgment of infringement, finding the patent claims at issue to be invalid under the on-sale bar of 35 U.S.C. § 102. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017). The Supreme Court granted Helsinn's petition for *cert*. Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 138 S. Ct. 2678 (June 25, 2018). The Supreme Court heard oral argument on December 4, 2018, and a decision is pending.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

The parties dispute the interpretation of two related claim terms, one in claim 4 of the '094 patent, and one in independent claim 1, on which claim 4 depends. Those two claims state:

> 1. A method for reducing the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising intravenously administering to a human in need thereof a pharmaceutical single-use, unit-dose formulation comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of

about 5.0.+-.0.5, said solution comprising: about 0.05 mg/mL palonosetron hydrochloride based on the weight of its free base; about 41.5 mg/mL mannitol; about 0.5 mg/mL EDTA; and a citrate buffer, wherein said formulation is stable at 24 months when stored at room temperature, and wherein said intravenous administration to said human occurs before the start of the cancer chemotherapy.

4. The method of claim 1, wherein said intravenous administration reduces the likelihood of delayed nausea and vomiting in said human.

The parties dispute the meaning of "reducing the likelihood" in claim 1, and "reduces the likelihood" in claim 4.[1] Both parties contend that the phrases have their ordinary meaning, but the parties disagree about what that ordinary meaning is. As to the phrase in claim 4, Helsinn proposes that it means, "prevents both delayed nausea and vomiting in a statistically significant number of patients;" Teva proposes that it means, "decreases the probability or makes it less probable that delayed CINV will occur."[2] The proposed constructions of "reducing the likelihood" in claim 1 are parallel.

Initially, Helsinn argues that Judge Cooper's claim construction in Helsinn v Hospira, Inc., Civil Action No. 15-2077, in which Judge Cooper adopted the same construction of "reduces the likelihood" as it proposes in this case, is correct and "should have ended the parties' current dispute." (Pl.'s Br. 2.) What Helsinn overlooks is that a major development has occurred since the district court decisions in the prior litigations: the Federal Circuit decided the

[1] Although the claim 1 phrase appears in the preamble, and the claim 4 phrase appears in the body of the claim, neither party contends that the preamble phrase does not limit the claim. Also, the parties' briefs do not distinguish the two phrases and have treated them as not presenting any material difference relevant to claim construction. The Court here follows suit.

[2] Whereas Helsinn uses the phrase "nausea and vomiting," and Teva uses the phrase "CINV," Helsinn's opening brief indicates that, in the context of this claim construction dispute, these phrases mean the same thing. (See Pl.'s Br. 1 n.1.)

appeal of the judgment of Civil Action No. 11-3962, and related cases, in Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1375 (Fed. Cir. 2017) ("Helsinn.") Judge Cooper's Markman construction was conducted without the benefit of the Federal Circuit's guidance in Helsinn. Helsinn is quite relevant to the claim construction dispute now submitted by the parties. This Court must therefore proceed to construe the claims in light of the Federal Circuit's binding decision.

As the present parties are well aware, in Helsinn, the Federal Circuit reviewed, *inter alia*, the standard applied by the district court in deciding whether four palonosetron formulation patents, including the '724 patent, were reduced to practice before the critical date. Id. at 1371. The Federal Circuit found that the district court had applied "too demanding a standard," and stated:

> The evidence is overwhelming that before the critical date of January 30, 2002, it was established that the patented invention would work for its intended purpose of reducing the likelihood of emesis.
>
> - The 1995 report from Study 2330 demonstrated that three different doses, including the 0.25 mg dose, produced statistically significant results at the 5% level for the median time it took patients to experience an emetic episode after administration of palonosetron. While this study did not show statistical significance for complete control of emesis or CINV for 24 hours, complete control is not a claim requirement. The invention is for reducing the likelihood of emesis, not necessarily completely preventing it, and the statistical significance for mean time to failure demonstrates that the product reduced the likelihood of emesis. Indeed, the Study 2330 final report concluded that the relevant dose of palonosetron "was effective in suppressing" CINV. *J.A.* 1636. Under our cases this is sufficient to establish that the invention here would work for its intended purpose of reducing the likelihood of CINV.

Id. at 1373.

While the '094 patent was not before the Federal Circuit, the '724 patent – which came

from the ’311 application that is a parent of the application that matured into the ’094 patent – was before the Court, and the section of the decision just quoted applies to the ’724 patent (as well as to the other palonosetron patents in that case.) This Court observes that the Federal Circuit addressed a strikingly similar issue to that raised by the parties in this claim construction dispute: did the claim language stating that the palonosetron invention was for reducing the likelihood of emesis require complete control or prevention of emesis? The Federal Circuit made clear that, in a related patent containing the same claim language, “complete control is not a claim requirement.” Id. The Federal Circuit thus ruled on an issue of claim construction: in the ’724 patent, “reducing the likelihood” of emesis does not mean completely preventing it. Id. Indeed, it implicitly held that a change in the median time for a patient to experience an emetic episode was sufficient to demonstrate that it “reduces the likelihood” of CINV.

Under Federal Circuit law, “we presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning.” Omega Eng’g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003). Thus, because the ’094 claim term presently at issue, “reducing the likelihood” of emesis, is the same as the term construed by the Federal Circuit in Helsinn, this Court presumes that it carries the same construed meaning.

As discussed below, Helsinn has failed to demonstrate that this presumption should be abandoned in favor of its own proposed construction.

The parties’ proposed constructions differ principally with regard to two issues: 1) does the claim language require prevention of delayed cancer chemotherapy-induced nausea and vomiting (“CINV”)?; and 2) does the claim language require that prevention of CINV be found

in a statistically significant number of patients?

In support of its proposed construction, Helsinn first points to a number of phrases in the specification of the ’094 patent. A first group of phrases addresses what certain prior art pharmaceuticals are “indicated” for: ondansetron (indicated for “prevention” of CINV) (col.2 ll.13-20); granisetron (indicated for “prevention of nausea and vomiting”) (col.2 ll.24-28); tropisetron (indicated for “treatment” of CINV) (col.2 ll.35-38); and dolasetron (indicated for “prevention” of CINV) (col.2 ll.39-43.) None of the cited phrases in this group refers to reducing something or reducing the probability of something. This Court does not see how these statements about the prior art might suggest to a skilled artisan that “reduces the likelihood of” in claim 4 means “prevents.” Nor do these statements say anything about a statistically significant number of patients.

Helsinn also points to a second group of phrases in the specification which characterize the present invention. With the exception of one phrase which describes the invention as a “formulation for the treatment and prevention of emesis” (col.2 ll.66-67), every other phrase in the specification describing the purpose of the invention states that it is for preventing or reducing emesis. ’094 patent, col.2 l.53; col.3 l.13; col.3 ll.22-23; col.3 l.36; col.4 l.60; col.5 ll.20-21; col.5 l.67. The patentees thus, in the specification, repeatedly and almost exclusively described the purpose of the invention to be “preventing or reducing emesis.” These specification statements do not support Plaintiff’s proposal that “reduces the likelihood” means “prevent.” First, these phrases say nothing about the likelihood of anything; they are all about preventing or reducing emesis, and do not refer to the likelihood of emesis. Second, to the extent that they suggest anything about the words “preventing” and “reducing,” they suggest that the

applicants understood preventing to differ from reducing. If preventing and reducing mean the same thing, these phrases are redundant.[3] Again, as already stated, this does not expressly speak to the matter of the *likelihood* of emesis.

Read as a whole, the specification teaches that the inventors understood the invention to have the purposes of preventing emesis as well as reducing emesis. This provides no support for Helsinn's contention that the skilled artisan would have understood "reduces the likelihood" to mean preventing something. Rather, it supports the proposition that the inventors understood "preventing emesis" and "reducing emesis" to mean different things.

Helsinn then argues:

> As Helsinn's expert, Dr. Saab, explained, . . . a POSA would have understood that antiemetics are incapable of preventing CINV in all patients. (Ex. 5, Saab Decl. at ¶¶ 24, 28.) Further, to obtain approval for an indication of CINV prevention, a POSA would have known that clinical studies needed to demonstrate that the setron being investigated was capable of preventing CINV in a statistically significant number of patients, and not in all patients. (Id. at ¶ 29.)

(Pl.'s Br. 9-10.) The Court makes two observations about this argument. First, Helsinn begins by asserting that, based on the specification disclosure of prior art setrons, as well as what a skilled artisan would have known about them, the skilled artisan would have understood "reduces the likelihood" to mean preventing CINV or delayed CINV in a statistically significant number of patients. However, Helsinn has pointed to nothing in the specification that discloses anything about treatment effects on statistically significant numbers of patients. Helsinn has offered no basis to link the specification's disclosure of the "indications" for prior art setrons to

[3] It seems much more likely that the applicants understood the purpose of the invention to include both preventing emesis and reducing emesis, rather than only one of those two. The key point here, though, is that the language of the specification supports the inference that the applicants did not equate preventing emesis with reducing emesis.

any particular method of assessing treatment effects.[4] Second, Helsinn attempts to make this link by asserting that the skilled artisan would have known that, to obtain FDA approval for an indication of CINV prevention, clinical studies needed to demonstrate that the setron being investigated was capable of preventing CINV in a statistically significant number of patients. This argument conflicts with the Federal Circuit's holding in Helsinn.

There, as discussed earlier, the Court held that the invention was for "reducing the likelihood of emesis, not necessarily completely preventing it . . ." Helsinn, 855 F.3d at 1373. The Federal Circuit considered whether "the invention would work for its intended purpose, which, according to the claims, is 'reducing the likelihood' of emesis and CINV." Id. at 1372. The Federal Circuit then stated:

> Our cases distinguish between the standard required to show that a particular invention would work for its intended purpose and the standard that governs FDA approval of new drugs, including the various stages of clinical trials. In patent law, the requisite testing, if any, for showing that an invention will "work for its intended purpose" varies depending on "the character of the invention," including the claim language and the "nature and complexity of the problem" the invention seeks to solve. . . .
>
> Approval of a new drug by FDA, however, is a more demanding standard than that involved in the patents-in-suit. The patents here make no reference to FDA standards and broadly claim a palonosetron formulation for reducing the likelihood of emesis and CINV. For FDA approval, however, an applicant must submit, *inter alia*, "adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use" and "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed." . . .
>
> Here, the district court based its finding that the invention was not reduced to practice before the critical date on insufficient testing for Helsinn to have

[4] If there is a logical connection between the "indications" for prior art setrons and a method for determining the treatment effects of those medications, Helsinn has not pointed it out.

> "determined that the invention would work for its intended purpose." The district court appeared to believe that Teva needed to meet the FDA standard, which requires finalized reports with fully analyzed results from successful Phase III trials. This is clear from the district court's reliance on the testimony of Helsinn's expert who "referred to FDA standards in forming his opinions in this case" and stated that FDA "articulated a statistical framework for being able to really know from the [clinical trial] data . . . that a drug is working." Throughout its opinion the district court found lack of reduction to practice for failure to establish "efficacy" under FDA standards, and the lack of fully analyzed Phase III studies as required by FDA. The district court was influenced particularly by the fact that FDA found the so-called Study 2330 insufficient to demonstrate efficacy.
>
> The district court clearly erred by applying too demanding a standard. The completion of Phase III studies and final FDA approval are not pre-requisites for the invention here to be ready for patenting.

Id. at 1372-73 (citations omitted).

In short, the Federal Circuit held that, when patents make no reference to the standards for FDA approval, it is error to import FDA standards into the reduction to practice inquiry. It necessarily follows that it would be error to import them into a claim limitation.

This Court finds no support for Helsinn's proposed construction in the specification of the '094 patent.

Helsinn next argues that the prosecution history supports its proposed constructions. Helsinn points to, *inter alia*, the prosecution history of "earlier-issued, related patents," one of which is U.S. Patent No. 7,947,724 (the "'724 patent").[5] This is correct, but does not fully capture the connection between the '724 patent and the '094 patent. In the "Related U.S. Application Data" section on the first page of the issued '094 patent, it states:

> This is a continuation of U.S. Ser. No. 13/901,437, filed May 23, 2013, which is a continuation-in-part of U.S. Ser. No. 13/087,012 filed Apr. 14, 2011, which is a continuation of U.S. Ser. No. 11/186,311 filed Jul. 21, 2005 (now U.S. Pat. No.

[5] As already discussed, the '724 patent was one of the patents at issue in Helsinn.

> 7,947,724), which is a continuation of PCT/EPO4/000888, filed Jan. 30, 2004, which claims priority to U.S. Provisional Application 60/444,351, filed Jan. 30, 2003.[6]

Thus, application no. 11/186,311 (the "'311 application") matured into U.S. Pat. No. 7,947,724. Application no. 13/902,132 derived from application no. 11/186,311 through a chain of continuation and continuation-in-part applications, and matured into the '094 patent.

The parties agree on the material facts regarding the prosecution history of the '724 patent. Some original claims in the '311 application recited a palonosetron solution for preventing or reducing emesis. For example, original claim 1 stated:

> 1) A pharmaceutically stable solution for preventing or reducing emesis comprising
> a) palonosetron or a pharmaceutically acceptable salt thereof and
> b) a pharmaceutically acceptable carrier,
> wherein the pharmaceutically acceptable carrier comprises mannitol.

(Ramirez Dec. Ex. G at 15.) The examiner rejected all of the initial claims under 35 U.S.C. § 112 "because the specification, while being enabling for a pharmaceutically stable solution for reducing emesis, does not reasonably provide enablement for preventing." (Office Action dated 8/30/2006 at 2, Ramirez Dec. Ex. H.) The applicants filed a response to this office action which states that, during a telephone conference with the examiner on July 27, 2006, there was a discussion of a different application, the '270 application, which dealt with, *inter alia*, the claim phrase "preventing" in a similar context. (Amendment and Response dated 2/26/2007 at 2, Ramirez Dec. Ex. I.) The response also stated:

> Applicant understood the Examiners' primary concern with the claims to be with the word "preventing," recited in independent Claims 1 and 11 of the '270

[6] This quote comes from the text version supplied on the patft.uspto.gov website, which differs slightly, but not materially, from the wording in the published, formatted patent.

> application. Applicant indicated that palonosetron has been approved by the Food and Drug Administration for preventing emesis, and is marketed as a drug for preventing emesis.
>
> The Examiners suggested that an amendment to independent Claims 1 and 11 in the '270 application, wherein Applicant includes the phrase "reducing the likelihood" of emesis instead of "preventing" emesis, would address the Office's concerns. Applicant has amended the claims in this application in accordance with the Examiners' suggestions for the '270 application.

(Id.) The response included amendments in which the applicants amended claim 1, removing "preventing," and adding, "or reducing the likelihood of emesis." (Id. at 3.)

Helsinn argues that these undisputed prosecution history facts should be interpreted as follows:

> By adopting the Examiner's suggested "reducing the likelihood" language, and relying upon Aloxi®'s FDA-approved indication for preventing CINV, Helsinn made explicit what a POSA would have readily understood from the specification's reference to the prevention of CINV, i.e., that the disclosed palonosetron formulations prevent CINV and delayed CINV in a statistically significant number of patients.

(Pl.'s Br. 13.) The Court does not understand Helsinn's logic here. Helsinn appears to contend that, by removing the word "preventing" and adding the phrase, "or reducing the likelihood of emesis." the applicants "made explicit" that the claimed formulations prevent CINV and delayed CINV in a statistically significant number of patients. First, there is nothing in the response (the remarks, the amended claims) that provides any foundation for the assertion about a statistically significant number of patients. The section in which the applicants traversed the rejection under 35 U.S.C. § 112 contains no reference to these concepts or anything close to them. (Amendment and Response dated 2/26/2007 at 11, Ramirez Dec. Ex. I.) Second, the proposition that removing the word "preventing" – and adding "reducing the likelihood" – made explicit either that the formulations prevent CINV or that a skilled artisan would understand that to be the case

defies conventional logic. Nothing in the applicant's response supports an inference that the applicants had this understanding, or that skilled artisans reading the amended application would have this understanding.

Teva, on the other hand, correctly argues that not only does the prosecution history *not* support Helsinn's proposed construction but, under the doctrine of prosecution disclaimer, Helsinn's proposed construction is barred. The key Federal Circuit case on prosecution disclaimer is Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-24 (Fed. Cir. 2003), in which the Court held:

> The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution. . .
>
> [W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender.

Furthermore, the Federal Circuit has held:

> Prosecution disclaimer "preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). "[F]or prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Id.* at 1325-26. "Thus, when the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim surrendered." *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013). Such disclaimer can occur through amendment or argument.

Aylus Networks, Inc. v. Apple Inc., 856 F.3d 1353, 1359 (Fed. Cir. 2017).

Here, the '311 applicants amended the claims by replacing "preventing" with "reducing the likelihood of emesis" in order to overcome an enablement rejection. This constitutes an unmistakable disclaimer of "preventing." Under the doctrine of prosecution history disclaimer,

the scope of the meaning of "reducing the likelihood of emesis" has been narrowed, and the applicants surrendered the meaning of "preventing emesis."

The '311 application is a parent application of the '094 patent, which descended from it through an unbroken chain of continuation and continuation-in-part applications. Defendants next argue that the disclaimer found in the prosecution of the '724 patent binds and restricts the interpretation of the same claim term in patents which matured from the descendant continuation and continuation-in-part applications. "When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999). In the instant case, multiple patents derived from the same initial application. Under Elkay, the disclaimer found in the prosecution history of the '724 patent applies to subsequently issued patents that contain the same claim limitation. The '724 patent and the '094 patent contain the same claim limitation, "reducing the likelihood."[7] The interpretation of the meaning of this term in the '094 patent is thus restricted by the unmistakable surrender of subject matter during prosecution of the '724 patent.

[7] The Court notes that, while the identical phrase, "reducing the likelihood," appears in claim 1 of the '724 patent and claim 1 of the '094 patent, these claims differ in the phrasing of what has a reduced likelihood. In claim 1 of the '724 patent, it is "emesis;" in claim 1 of the '094 patent, it is "cancer chemotherapy-induced nausea and vomiting." No one has suggested that the difference in the wording that follows the phrases affects the prosecution disclaimer analysis. Nor has Helsinn argued that it rescinded the disclaimer. Both patents are directed to the use of palonosetron to reduce cancer chemotherapy-induced nausea and vomiting. The abstract of the '724 patent is identical to the abstract of the '094 patent. Both state: "The present invention relates to shelf-stable liquid formulations of palonosetron for reducing chemotherapy and radiotherapy induced emesis with palonosetron." The disclaimer arising in the prosecution of the '724 patent applies to the identical phrase in the '094 patent.

"A patentee of course may not recapture during litigation subject matter that was ultimately rejected as unpatentable during prosecution." TorPharm Inc. v. Ranbaxy Pharm., Inc., 336 F.3d 1322, 1329 (Fed. Cir. 2003). Helsinn's proposed construction of "reducing the likelihood" as "preventing" is barred by the doctrine of prosecution history disclaimer.

Helsinn next argues that scientific references submitted during prosecution of the '094 patent support Helsinn's proposed construction. In short, the applicants submitted reports of research studies on prior art setrons in which concepts of statistical significance and prevention of CINV were referenced. Helsinn does not articulate a theory of claim construction on this point. Evidence that the applicants submitted reports of research studies in which concepts of statistical significance and prevention of CINV were referenced does not, without more, confirm that a skilled artisan, reading the '094 patent, would understand "reducing the likelihood of emesis" to have the meaning that Helsinn proposes.

Last, Helsinn offers the testimony of its expert, Dr. Saab, who makes conclusions that do support Helsinn's proposed construction. On the role of expert testimony in claim construction, the Supreme Court has held:

> In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. *See, e.g., Seymour v. Osborne*, 78 U.S. 516, 11 Wall. 516, 546, 20 L. Ed. 33 (1871) (a patent may be "so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning"). In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the "evidentiary underpinnings" of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.
>
> For example, if a district court resolves a dispute between experts and makes a factual finding that, in general, a certain term of art had a particular meaning to a

> person of ordinary skill in the art at the time of the invention, the district court must then conduct a legal analysis: whether a skilled artisan would ascribe that same meaning to that term in the context of the specific patent claim under review. That is because experts may be examined to explain terms of art, and the state of the art, at any given time, but they cannot be used to prove the proper or legal construction of any instrument of writing.

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015) (citations omitted). Helsinn's use of expert testimony here does not conform to these principles. The key problem is that Helsinn has not established the predicate, that there is a need for this Court to consult extrinsic evidence to understand the meaning of a term in the relevant art. Helsinn has pointed to nothing in the claim language that appears to be a technical term or a term of art.[8] The cited portions of Dr. Saab's declaration do not even contend that "reducing the likelihood" is a term of art or a technical term. (Saab Dec. ¶¶ 27-30.) The statements cited by Helsinn are merely conclusory statements of support for their proposed construction. They do not support the proposition that "reducing the likelihood" is a term of art in the pharmaceutical arts. Under the principles stated by the Supreme Court in Teva, Helsinn has not persuaded that the Court needs to look beyond the intrinsic evidence to fully understand the meaning of "reducing the likelihood."

Teva proposes that the "reducing the likelihood" claim phrases do not need any construction and have their plain and ordinary meaning, which is "decreasing the probability." Teva contends that the intrinsic record supports its plain meaning construction. Teva observes that the specification does not expressly define "reducing the likelihood." Also, as already

[8] Nor does this Court find any other basis to consider extrinsic evidence here. "Extrinsic evidence may not be used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283, 1290 (Fed. Cir. 2015). This Court finds that the meaning of the claim phrases at issue is unambiguous in light of the intrinsic evidence. Extrinsic evidence may not be used to contradict this.

discussed, Teva points to the fact that the specification treats "preventing" and "reducing" as distinct terms with distinct meanings. Furthermore, Teva observes that, as to delayed CINV, the only form of CINV specified in claim 4, the specification uses only the term, "reduce." The first two of these three points appear to be both correct and meaningful observations. The third point carries little weight because – as Teva has just pointed out – the specification repeatedly states that the invention is for preventing or reducing emesis, and emesis is a broader category that includes delayed emesis. Nonetheless, Teva is correct that the specification does not expressly define "reducing the likelihood" and treats "prevent" and "reduce" as not synonymous. This second point weighs against Helsinn's proposed construction.

Next, Teva points to the fact that the specification says nothing about statistical significance or statistically significant numbers of patients. This is true. Teva argues as well that, given the absence of anything in the patent regarding statistical significance, accepting Helsinn's proposed construction would create an area of significant ambiguity and uncertainty: what is a statistically significant number of patients? The specification provides no answers to that question.

This Court concludes that "reducing the likelihood" in claim 1 and "reduces the likelihood" in claim 4 of the '094 patent have their ordinary meaning. This Court adopts Teva's proposed construction that these phrases mean decreasing the probability of the condition described.

SO ORDERED.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: December 21, 2018